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**From:** McNally, Robert [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EFA5514317E34B9895687D73730FDDE9-ROBERT MCNALLY]  
**Sent:** 2/16/2017 7:56:52 PM  
**To:** Nalubola, Ritu [Ritu.Nalubola@fda.hhs.gov]  
**CC:** Mendelsohn, Mike [mendelsohn.mike@epa.gov]; Hartman, Mark [Hartman.Mark@epa.gov]; Leahy, John [Leahy.John@epa.gov]  
**Subject:** Oxitec -- next steps

**Importance:** High

Ritu,

We are fine with delivering this short message below for the call on Friday.

Convey to Keith Matthews:

- 1) EUP/Sec 5 and relevant conditions, incl. that it is a path the firm can immediately proceed with and that EPA can issue the EUP before 236 is final;
- (2) Intrexon can immediately submit a Section 18 and EPA can begin review, but that 236 would have to be final before EPA grants the Section 18; and
- (3) EPA and FDA are ready to have a joint meeting with firm as soon as the firm is available (as early as next week) to discuss additional details.
- (4) We have collaborated with FDA extensively, but we defer to FDA, who will contact Intrexon later this morning to discuss FDA issues separately.
- (5) Suggest that we should discuss EPA-FDA intersects at the joint meeting.

How does this sound?

Mike M will call Keith early in AM, since I am on leave. He may have Elizabeth M join him.

Thanks

Bob